NOV 29 2010

K102360

5. 510(K) SUMMARY

IceCure's IceSense3 device

Name and Address of Applicant:

IceCure Medical LTD.

Haeshel 7, Caesarea I.P. 38900, Israel

Elisabeth Sadka, VP RA QA clinical

Telephone: 972-4-6230333

Fax: 972-4-6230222

Contact Person and Phone Number:

Zvi Ladin, Ph.D., Principal, Boston MedTech Advisors

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Date Prepared: November 21, 2010

Name of Device

Trade/Proprietary Name: IceCure Medical, IceSense3 device

Common Name: Cryosurgical unit and accessories

Classification Name: Cryosurgical unit and accessories (21 C.F.R. § 878.4350).

Manufacturing Facility

IceCure Medical LTD.

Haeshel 7, Caesarea I.P. 38900, Israel

Predicate Devices

The IceSense3 System is substantially equivalent to the cleared IceSense™ System (K072883), the cleared Galil Medical Seednet family (K052530) and Sanarus Medical's V2 Treatment System (K062896).

Intended Use / Indications for Use

The IceSense3 is intended for cryogenic destruction of tissue during surgical procedures. The IceSense3 is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, thoracic surgery, gynecology, oncology, proctology, and urology. The IceSense3 may be used with an ultrasound device to provide real-time visualization of the cryosurgical procedure.

Urology

- *The system may be used to ablate prostatic tissue.*
- *The system may be used for the ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia*

Oncology

- *The system may be used for ablation of cancerous or malignant tissue.*
- *The system may be used for ablation of benign tumors.*
- *The system may be used for palliative intervention.*

Dermatology

- *The system may be used for the ablation or freezing of skin cancers and other coetaneous disorders.*

Gynecology

- *The system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.*

General Surgery

- *The system may be used for the ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions.*
- *The system may be used for the destruction of warts or lesions.*

- *The system may be used for the palliation of tumors of the oral cavity, rectum, and skin.*
- *The system may be used for Ablation of breast fibroadenomas*

Thoracic Surgery

- *The system may be used for the ablation of arrhythmic cardiac tissue.*
- *The system may be used for the ablation of cancerous lesions*

Proctology

- *The system may be used for the ablation of benign or malignant growths of the anus and rectum*
- *The systems may be used for the ablation of hemorrhoids.*

Technological Characteristics

The IceSense3 device is used to destroy unwanted tissue by application of extreme cold to the selected sites. The device delivers cold temperatures to targeted tissue by pressurized liquid nitrogen closed system and a disposable cryoprobe. Various cryoprobes are available.

The device consists of a main chassis for the cooling system, a controller, a touch screen, a foot pedal and a cryohandle that controls the system and holds the probe.

Safety measures of the system include alarms, safety valve, emergency button and automatic abortion of the procedure in case of technical malfunction.

Performance Data

The performance of the IceSense3 is in the range of metrics performance of the predicate devices, in the range of up to 15 minutes freeze, the IceSense3 system probes can create an iceball of at least 40mm diameter. Performance testing of IceSense3, included testing of the shaft temperature during freeze, thaw and warm phases. Results demonstrated that temperatures along the shaft remained within the device's specifications during all phases. Performance testing of IceSense3 versus the Sanarus Visica2 system that are both based on liquid nitrogen technology were conducted and gave very similar metrics of iceball formation versus time; the temperatures at the tip of the probe were very similar as well.

In all instances, the IceSense3 functioned as intended and the performance observed was as expected.

Substantial Equivalence

The IceSense3 device is as safe and effective as the cleared IceSense™ System (K072883), the cleared Galil Medical Seednet family (K052530) and the cleared Sanarus Medical's V2 Treatment System (K062896).

The IceSense3 device has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor technological differences between the IceSense3 device and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the IceSense3 device is as safe and effective as the cleared IceSense™ System (K072883), the cleared Galil Medical Seednet family (K052530) and the cleared Sanarus Medical's V2 Treatment System (K062896).

Thus, the IceSense3 is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

NOV 29 2010

IceCure Medical, Ltd.
% Boston MedTech Advisors
Zvi Ladin, Ph.D.
990 Washington Street, Suite 204
Dedham, Massachusetts 02026

Re: K102360
Trade/Device Name: IceCure Medical IceSense3
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: October 28, 2010
Received: October 29, 2010

Dear Dr. Ladin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

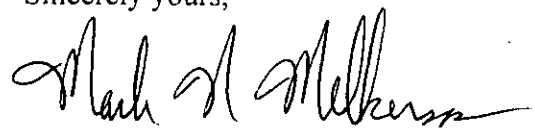
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

Gynecology

- *The system may be used for the ablation of malignant neoplasia or benign dysplasia of the female genitalia.*

General Surgery

- *The system may be used for the ablation of leukoplakia of mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions.*
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Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

Indications for Use Statement

510(k) Number (if known): K102360

Device Name: IceCure Medical IceSense3

Indications for Use:

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Dermatology

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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K102360

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